



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,028	03/14/2005	Christopher M. Starr	7685-93	1759
1059 7590 05/09/2007 BERESKIN AND PARR 40 KING STREET WEST BOX 401 TORONTO, ON M5H 3Y2 CANADA			EXAMINER SRIVASTAVA, KAILASH C	
			ART UNIT 1657	PAPER NUMBER
			MAIL DATE 05/09/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/501,028	<b>Applicant(s)</b> STARR ET AL.	
	<b>Examiner</b> Dr. Kailash C. Srivastava	<b>Art Unit</b> 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### Claims Status

1. Claims 1-29 are pending.
2. Your application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) is assigned to Art Unit 1657. To aid in correlating any papers for this application (i.e., 10/501,028), all further correspondence regarding this application should be directed to Art Unit 1657.
3. The assigned Examiner to your application under prosecution at the USPTO is Dr. Kailash C. Srivastava. To aid in correlating any papers for this application (i.e., 10/501,028), all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

### *Election /Restriction*

4. This application contains the following groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372.

- Group I Consisting of Claims 1-20,
  - a. Consisting of claims 1-13, drawn to a method to treat a subject having a lysosomal storage disease via administering to said subject a composition comprising a p97 molecule covalently linked to a protein; and
  - b. Consisting of Claims 14-20 drawn to a composition comprising a p97 molecule covalently linked to a protein.
- Group II, consisting of claims 21-26 drawn to another method to screen a compound having a therapeutic activity to treat a lysosomal storage disease.
- Group III, consisting of claims 27-29 drawn to a pharmaceutical composition in a unit dose format comprising pharmaceutically effective amount of a compound comprising a p97 molecule covalently linked to a protein

### **Inventions are Independent and Distinct**

5. The inventions listed as Groups I-III are each drawn to two different methods and two different compositions. Said inventions despite sharing a common item, i.e., a compound comprising p97 molecule linked to a protein, do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical features of the invention in group I method is to treat a patient suffering from a lysosomal storage disease via administering a composition. This method, however, does not advance the pertinent art because delivery of a therapeutic biomolecule to a particular body compartment or targeted cell via linking said biomolecule (e.g., melanotransferrin or p97) or a pharmaceutical to p97 (US2002/0119095 A1, Claims 1-31) is an art-known technique (See, e.g., U.S. Patent 7,179,617).

Giving the broadest interpretation from the claim language, the special technical feature of the invention in Group II is another method to screen for a compound, whereas the special technical feature of the composition in inventive Group III is a pharmaceutical composition. Thus, each one of the three inventive groups outlined above, despite sharing a common component (i.e., p97 molecule), has a different inventive concept by virtue of functionality residing in each of the inventive Groups. Group II invention is a method with the effect of identifying a compound and in Group III the invention is drawn to a composition. The Group I invention has an entirely different functionality effect, that of treating a subject suffering from a disease and the p97 molecule is merely a component in treating that disease. Thus, each of the inventive groups are functionally different from the other. Since no special technical feature exists among the inventions in groups I-III, there is no unity of invention.

### **Species Election**

6. This application contains claims directed to different composition comprised of a variety of ingredients. Therefore, if the applicants elect invention in any one of the Groups I-III above, the applicants must also make election of species by electing only one component from each of the categories listed below as applicable to applicants' elected invention for further prosecution.

- (i) Only one disease among those listed in Claim 12; and
- (ii) Only one protein among those listed in Claims 13, 20, or 29;

7. Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR §1.143).


In accordance with 37 CFR §1.499, Applicants are required that a reply to this requirement must also include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election of an invention along with the election of a species. Upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR §1.141. If claims are added after the election, Applicants must indicate which are readable upon the elected species [MPEP § 809.02(a)].


8. Applicants are reminded that upon the cancellation of claims to a non-elected invention and species, the inventorship must be amended in compliance with 37 CFR §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(I).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Kailash C. Srivastava, Ph.D.  
Patent Examiner  
Art Unit 1657  
(571) 272-0923  
3 May 2007

  
RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200